

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/667,848-Conf. #1385
Filing Date	September 22, 2003
First Named Inventor	Edward F. Ikeguchi
Art Unit	4143
Examiner Name	Not Yet Assigned
Attorney Docket Number	NY-MSI 203-US

Sheet	1	of	2
-------	---	----	---

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

IDS (Citation) by Applicant (3 References)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EM 155745465 US, on the date shown below in an envelope addressed to:
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: 1/16/07

Signature: Fani Malikouzakakis (Fani Malikouzakakis)

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/667,848-Conf. #1385
				Filing Date	September 22, 2003
				First Named Inventor	Edward F. Ikeguchi
				Art Unit	4143
				Examiner Name	R. J. RAJ
Sheet	2	of	2	Attorney Docket Number	NY-MSI 203-US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	DELGADO-HERRERA LETICIA, et al., "A model for the interim analysis process: a case study," CONTROLLED CLINICAL TRIALS, vol. 24, (February 2003), pages 51-65	√
	CB	DEMETS D. L. et al., "The agnosing negative trend in monitoring of clinical trials," LANCET THE, LANCET LIMITED. LONDON, GB, pages 1983-1988 (December 4, 1999)	√
	CC	FLEMING Thomas R., et al., "Monitoring of clinical trials: Issues and Recommendations," CONTROLLED CLINICAL TRIALS, vol. 14, pages 183-197 (1993)	√

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.